BZ

JS 44 (Rev. 12/07) (cand rev 1-16-08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

I. (a) PLAINTIFFS

Dephlia Davis, Rhea Davis and Jesse Gaynor

DEFENDANTS

Actavis Group hf; Actavis Totowa, LLC; Mylan, Inc.; Mylan Pharmaceuticals, Inc.; and UDL Laboratories, Inc.

(b) County of Residence of First Listed Plaintiff (EXCEPT IN U.S. PLAINTIFF CASES)

Marin County, California

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED. Hafnarfjodur, Iceland

(c) Attorney's (Firm Name, Address, and Telephone Number)

Attorneys (If Known)

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II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from another district (specify) | ☐ 6 Multidistrict Litigation | ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity):**
28 U.S.C. § 1332

Brief description of cause:
Wrongful death as a direct result of ingesting the prescription drug Digitek.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $**

CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE". See Notice of Pendency of Other Actions or Proceedings Submitted herewith.

IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2) (PLACE AND "X" IN ONE BOX ONLY)

☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE

DATE
July 1, 2008

SIGNATURE OF ATTORNEY OF RECORD
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Attorneys for Plaintiffs Dephlia Davis, Rhea Davis and Jesse Gaynor

IN THE UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

DEPHLIA DAVIS, RHEA DAVIS AND JESSE GAYNOR,

Plaintiffs,

v.

ACTAVIS GROUP hf; ACTAVIS TOTOWA, LLC; MYLAN, INC.; MYLAN PHARMACEUTICALS, INC.; and UDL LABORATORIES, INC.,

Defendants.

CV 08 3173

CASE NO.

COMPLAINT FOR DAMAGES PURSUANT TO WRONGFUL DEATH BASED UPON: BZ

1. **BREACH OF EXPRESS WARRANTY**
2. **BREACH OF IMPLIED WARRANTY**
3. **STRICT PRODUCT LIABILITY (FAILURE TO WARN)**
4. **STRICT PRODUCT LIABILITY (MANUFACTURING DEFECT)**
5. **FRAUD AND DECEIT**
6. **NEGLIGENT MISREPRESENTATION**
7. **NEGLIGENCE & NEGLIGENCE PER SE**
8. **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

DEMAND FOR JURY TRIAL

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Plaintiffs Dephlia Davis, Rhea Davis and Jesse Gaynor, upon information and belief, based upon *inter alia* the investigation made by Plaintiffs, by and through their attorneys, state, aver and allege as follows:

I. INTRODUCTION

1. Plaintiffs Dephlia Davis, Rhea Davis and Jesse Gaynor, as heirs of William Davis, deceased, bring this action pursuant to the provisions of Code of Civ. Proc. § 377.60 to recover for the wrongful death of William Davis who died as a direct result of ingesting the prescription drug Digitek®.

2. Digitek®, generic name digoxin, is a prescription heart medication designed, developed, manufactured, tested, advertised, marketed, distributed, promoted and sold by Defendants Actavis Totowa LLC; Mylan, Inc.; Mylan Pharmaceuticals, Inc.; and UDL Laboratories, Inc. It is an antiarrhythmic agent widely prescribed to patients with congestive heart failure and irregular heartbeat such as atrial fibrillation and atrial flutter.

3. At all relevant times, Defendants touted Digitek® as a safe and effective heart medication even though Defendants knew, or had a reason to know, that Digitek® was defective and had dangerous and life threatening side effects, which could result in serious injury or death. Defendants watered down and/or diluted the actual risk and safety concerns associated with the use of Digitek® from decedent William Davis, the medical community, and the public at large. Defendants placed profits at the expense of consumer safety.

4. On April 25, 2008, Defendant Actavis Totowa initiated a nationwide recall of all strengths of Digitek® tablets because the drug was commercially released with twice the approved level of digoxin, the drug's active ingredient, than is appropriate. Defendants' actions caused thousands of individuals to sustain debilitating and lethal injuries. William Davis, with no contributory negligence on his part, ingested Digitek® as prescribed to him and sustained serious injuries resulting in his death.

II. JURISDICTION AND VENUE

5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs,

and because this is an action by Plaintiffs who are a resident of a different state from the Defendants.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1391. William Davis purchased and consumed Digitek® in the Northern District of California, which served as a legal cause of his injuries and damages hereafter alleged. Additionally, Defendants promoted and/or advertised the benefits of this drug in this District, and made material omissions, misrepresentations and breaches of warranties concerning the safety and/or fitness of the drug in this District.

III. PARTIES

A. Plaintiffs

7. Plaintiff Dephlia Davis is, and at all relevant times herein mentioned was, a loving and devoted wife of decedent William Davis. Plaintiff brings this action in her capacity as a surviving wife and heir. Decedent William Davis was, at all relevant times prior to his death, a dedicated and loving husband to Plaintiff. At all relevant times herein, Plaintiff Dephlia Davis is and was a resident of Marin County, California.

8. Plaintiff Rhea Davis is, and at all relevant times herein mentioned was, a loving and devoted daughter of decedent William Davis. Plaintiff brings this action in her capacity as a surviving child and heir. Decedent William Davis was, at all relevant times prior to his death, a dedicated and loving father to Plaintiff. At all relevant times herein, Plaintiff Rhea Davis is and was a resident of Marin County, California.

9. Plaintiff Jesse Gaynor is, and at all relevant times herein mentioned was, a loving and devoted son of decedent William Davis. Plaintiff brings this action in his capacity as a surviving child and heir. Decedent William Davis was, at all relevant times prior to his death, a dedicated and loving father to Plaintiff. At all relevant times herein, Plaintiff Jesse Gaynor is and was a resident of Marin County, California.

B. Defendants

10. Defendant Actavis Group hf is an international pharmaceutical company, with its principal place of business at Dalshraun 1 220 Hafnarfjodur, Iceland, and regularly conducts business throughout the United States and specifically in California, including but not limited to directing the operation and management of Defendant Actavis Totowa LLC.

11. Defendant Actavis Totowa, LLC, (hereinafter "Defendants" or "Actavis Totawa"), is a corporation, incorporated and existing under the laws of the State of Delaware, with its principal place of business located at 990 Riverview Drive, Totowa, New Jersey.

12. Defendant Mylan, Inc., (hereinafter "Defendants" or "Mylan") is a corporation, incorporated and existing under the laws of the state of Pennsylvania, with its principle place of business located at 1500 Corporate Drive, Canonsburg, Pennsylvania.

13. Defendant Mylan Pharmaceuticals, Inc., (hereinafter "Defendants" or "Mylan Pharmaceuticals") is a corporation, incorporated and existing under the laws of the state of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia.

14. Defendant UDL Laboratories, Inc., (hereinafter "Defendants" or "UDL") is a corporation, incorporated and existing under the laws of the State of Illinois, with its principle place of business located at 1718 Northrock Court, Rockford, Illinois.

15. At all relevant times, Defendants were engaged in the business of formulating, designing, manufacturing, testing, labeling, promoting, marketing, distributing and/or selling Digitek® in the stream of interstate commerce with the intention and/or reasonable expectation that the drug would be sold and/or used in California. Said drug did ultimately reach consumers in the State of California, causing residents in this State to be exposed to significantly increased health hazards and injuries, including the injury and damages to decedent and Plaintiffs as alleged herein.

C. Agency, Aiding & Abetting

16. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of other unnamed parties and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other parties, knowing that their conduct constituted a breach of duty.

17. At all material and relevant times mentioned herein, Defendants, themselves or by use of others, did manufacture, create, design, formulate, test, label, sterilize, promote, package,

distribute, supply, market, sell, advertise, warn and/or otherwise distribute in interstate commerce the prescriptive drug Digitek®.

18. At all material and relevant times mentioned herein, each of the Defendants was the co-conspirator, agent and/or employee of each of the remaining unnamed parties and was at all relevant times acting within the course and scope of such conspiracy, agency, venture and/or employment.

IV. FACTUAL BASIS FOR THE CLAIMS ASSERTED

19. Digitek® is one of the brand names for the generic drug digoxin. Digoxin, also known as Digitalis, is a purified cardiac glycoside extracted from the foxglove plant. It is part of a group of drugs widely used for the treatment of various heart conditions, including congestive heart failure and abnormal heart rhythms, such as atrial fibrillation and atrial flutter.

20. Digoxin is used to increase the strength and vigor of heart muscle contractions and is used in the treatment of congestive heart failure, abnormal heart rhythm and other heart ailments.

21. Digoxin has a narrow therapeutic maintenance dosage rate, meaning there is very little margin between drug effectiveness and drug toxicity.

22. Digoxin toxicity can occur from a single exposure or chronic overmedication. And, digoxin toxicity can cause life threatening heart rhythm disturbances, cardiac instability, irregular pulse, heart palpitations, bradycardia as well as nausea, vomiting, diarrhea, dizziness, confusion, loss of appetite, visual disturbances, low blood pressure and even death.

23. The Digitek® tablets were manufactured by Defendant Actavis Totawa.

24. The Digitek® tablets were distributed by Defendant Mylan Pharmaceuticals under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

25. Digitek® was approved for sale and distribution in the United States only in the following two dosages: (1) Digitek® (digoxin tablets, USP) 0.125 mg; and (2) Digitek® (digoxin tablets, USP) 0.250 mg.

26. Both dosages of Digitek® are approved by the FDA for sale and distribution if the dose contains the labeled amount of digoxin. Digitek® tablets manufactured and distributed with an amount of digoxin in excess of the labeled dose are not approved for sale or distribution.

27. On April 25, 2008, the FDA announced that Actavis Totowa had initiated a Class I nationwide recall of all strengths of Digitek® tables because the tablets were manufactured and released with twice the thickness as normal, and therefore, contained twice the approved level of digoxin.

28. Numerous reports of illnesses and injury resulting from the use of Digitek® have been reported to the Food and Drug Administration (FDA).

A. Defendants Failed to Comply With the Required Safety Guidelines

29. "Good Manufacturing Practices" are standard guidelines set out by the FDA to ensure drug development is carried out in a safe and quality process to avoid contamination and ensure repeatability.

30. Defendants purported to verify the adherence of their drug manufacturing and development operations to the FDA's "Good Manufacturing Practice" regulations. When in reality, Defendants failed to follow the guidelines set out by the FDA, even after they were warned of their failure to follow these guidelines.

B. The August 15, 2006 FDA Warning Letter

31. Some, if not all, of the recalled Digitek® was designed, developed, manufactured, produced, sold, marketed, labeled, packaged, dosed, advertised, supplied and/or distributed from a plant in Little Falls, New Jersey owned by Defendant Actavis Totowa and/or its affiliates.

32. In January and February 2006, the FDA conducted an inspection of Actavis Totowa's facilities in New Jersey. As a result of this inspection, the FDA issued a "Warning Letter" to Actavis Totowa concerning its failure to comply with the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder.

33. According to the FDA's August 2006 Warning Letter, the inspection, among other things, revealed that there were six potentially serious and unexpected adverse drug events for products, including digoxin, that were not reported to the FDA. In addition, the letter noted that Actavis Totowa failed to file periodic safety reports, which resulted in at least 26 adverse drug experiences, which were never reported, and that Actavis Totowa had not developed procedures for the surveillance, receipt, evaluation and report of adverse events.

34. The August 2006 Warning Letter stated, in particular, the following:

> Deviations demonstrating your firm's failure to comply with 21 CFR §§ 314.80, 314.98, and 310.305, which were observed during the inspection, include the following: (21 CFR § 314.98 requires applicants holding an approved abbreviated new drug application (ANDA) to comply with certain reporting and record keeping requirements of 21 CFR § 314.80. Thus, deviations demonstrating your firm's failure to comply with 21 CFR § 314.98 are described in relation to 21 CFR § 314.8)
>
> 1) Failure to submit to the Food and Drug Administration (FDA) ADE reports as required by 21 CFR §§ 314.80(c)(1) and 314.98(a) and 310.305(c). Specifically, there were six potentially serious and unexpected adverse drug events dating back to 1999 for products such as Digoxin, ... that were not reported to FDA.
>
> ***
>
> 4) Your firm has never filed a periodic safety report as required by 21 CFR 314.80(c)(2) and 314.98(a). The inspection found that your firm is not following procedures that were established for filing periodic safety reports. This failure to submit periodic safety reports has resulted in at least twenty-six ADEs which were never reported to FDA.
>
> 5) Procedures for the surveillance, receipt, evaluation, and reporting of adverse events have not been developed as required by 21 CFR 314.80(b), 314.98(a), and 310.305(a). Specifically, your firm lacks procedures regarding follow-up investigations, adequate completion of the MedWatch form (FDA Form 3500A), maintenance of records to assure timely submission of 15-day reports, and evaluation of adverse event data for serious outcome and event expectedness.
>
> ***
>
> The specific violations noted in this letter are serious and may be symptomatic of underlying problems. You are responsible for investigating and determining the causes of the violations identified above and preventing recurrence of similar violations.

C. The February 1, 2007 "Revised Warning Letter"

35. Between July 10 and August 10, 2006, the FDA conducted another inspection of the Actavis Totowa's facilities in New Jersey. As a result of such inspection, on or about February 1, 2007, the FDA issued a "Revised Warning Letter" to Actavis Totowa citing, "significant deviations from the [FDA's] current Good Manufacturing Practice regulations."

36. In the Revised Warning letter, the FDA noted several deviations from Good Manufacturing Practices, resulting in the adulteration of drug products manufactured by Actavis

Totowa that were observed by the FDA during the inspection. In relevant part, the FDA's Revised Warning Letter stated the following:

> During the inspection, our investigators documented significant deviations from the current Good Manufacturing Practice (cGMP) regulations set forth in Title 21, *Code of Federal Regulations*, Parts 210 and 211, in conjunction with your firm's manufacture of prescription drug products.
>
> The inspection revealed that drug products manufactured in your facility are adulterated within the meaning of 21 U.S.C. §351(a)(2)(B), Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to your firm on a FDA-483, List of Inspectional Observations, at the close of the inspection on August 10, 2006.
>
> The significant observations included, but were not limited to, the following:
>
> 1. Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there **is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.**
>
> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.
>
> Numerous instances were observed where manufacturing process deviations occurred and in-process specifications were not met, yet there is no indication that action was taken promptly to investigate or to correct the deviations and the products were approved for release and distribution by your quality control unit. Additionally, instances were noted where your firm's quality control unit reviewed and approved test data and reports that were inaccurate and incomplete, and as such, did not follow established procedures. [21 CFR 211.22(a) and 21 CFR 211.22(d)]
>
> ***
>
> 7. Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:

> a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: ... **Digoxin Tablets, USP, 0.25mg.**
>
> ***
>
> 8. Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186(b)(9) and 21 CFR 211.188(b)(10)]
>
> ***
>
> [W]e are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality, and purity.
>
> ***
>
> The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

(Emphasis added.)

D. Defendant Actavis Totowa Instituted a Class I Recall of Digitek®

37. On or about April 25, 2008, the FDA announced that Defendant Actavis Totowa had instituted a Class I Recall of all lots of Digitek®. The FDA announcement included the following information:

> Morristown, NJ -- April 25, 2008 -- Actavis Totowa LLC, a United States manufacturing division of the international generic pharmaceutical company Actavis Group, is initiating a Class I nationwide recall of Digitek® (digoxin tablets, USP, all strengths) for oral use. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

> The voluntary all lot recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released. These tablets may contain twice the approved level of active ingredient than is appropriate.
>
> Digitek® is used to treat heart failure and abnormal heart rhythms. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can also result from excessive Digitalis intake. Several reports of illnesses and injuries have been received.
>
> Actavis manufactures the products for Mylan and the products are distributed by Mylan and UDL under the Bertek and UDL labels. Bertek and UDL are affiliates of Mylan.

38. Class I recalls are the most severe type of FDA recalls because they are instituted only when there exists a potential risk that use of the product may lead to a serious injury or death.

39. The recalled Digitek® was defective and posed a risk of serious injury and death to decedent William Davis and the public at large. Defendants placed tens of thousands, if not millions, of patients, including William Davis, at risk and caused personal injuries and harm, including medical expenses induced from ingesting or potentially ingesting a defective drug.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Breach of Express Warranty)

As for a First Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege as follows:

40. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

41. At all times herein mentioned, Defendants expressly warranted to members of the general public, including William Davis, and to the medical professionals by and through statements made by Defendants herein, its authorized agents and/or sales representatives, both orally and in publications, brochures, package inserts and/or other written materials intended for medical professionals, pharmacists, patients and/or the general public, that Digitek® was a safe, effective and fit heart medication and/or was proper for its intended use to manage, treat and/or control congestive heart failure, irregular heartbeat and other heart ailments. Said express warranties were part of the

marketing and sales of said drug, in that Defendants warranted the safety and efficacy of the drug's intended use to control pain.

42. Digitek® failed to conform to these express representations and/or warranties because some tablets of the recalled Digitek® contained twice the digoxin approved by the FDA, and the existence of double the strengthin the tablets posed a threat of digitalis toxicity, which can cause life threatening heart rhythm disturbances, nausea, vomiting, diarrhea, dizziness, confusion, loss of appetite, visual disturbances, low blood pressure, cardiac instability, bradycardia and even death.

43. In ingesting Digitek®, Davis and/or his prescribing healthcare professionals relied on the representations and foregoing express warranties concerning the safety and efficacy of the drug made by the Defendants. Said representations and warranties were inaccurate, false and/or misleading in that the use of the double strength tablets of Digitek® was known to have produced ill side effects, as set forth above.

44. As a legal result of the foregoing breach of express warranties by the Defendants, Davis ingested Digitek® and died, and Plaintiffs have suffered the injuries and damages herein alleged.

45. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

46. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

47. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

SECOND CAUSE OF ACTION

(Breach of Implied Warranty)

As for a Second Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

48. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

49. At all times herein mentioned, and prior to the time that the aforementioned drug product was used by Davis, Defendants impliedly warranted to members of the public, including Davis and healthcare professionals that the pharmaceutical drug Digitek® was of merchantable quality, safe and/or fit for the intended use to treat and/or control congestive heart failure, irregular heartbeat and other heart problems.

50. At all times that Defendants herein designed, manufactured, formulated, marketed, distributed, tested, inspected, promoted, and/or sold Digitek® for use by Davis, said Defendants had actual or constructive knowledge of the particular purpose for which this drug was to be used by the public, including Davis.

51. At all times that Defendants herein designed, manufactured, formulated marketed, distributed, tested, inspected, promoted, and/or sold Digitek®, Defendants knew or had reason to know that Davis, who was unskilled in the research, design, manufacture, inspection, testing and/or efficacy of Digitek®, was relying on and, in fact, did rely on said Defendants' implied warranties.

52. As a legal result of the foregoing breach of implied warranties by the Defendants, Davis ingested Digitek® and died, and Plaintiffs have suffered the injuries and damages herein alleged.

53. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

54. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

55. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

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THIRD CAUSE OF ACTION

(Strict Liability Failure to Warn)

As for a Third Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

56. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

57. At all times mentioned, Defendants were engaged in the business of researching, licensing, designing, testing, manufacturing, producing, processing, assembling, formulating, inspecting, marketing, labeling, promoting, packaging, warning, advertising and/or distributing Digitek® in the State of California.

58. At all times relevant, Digitek® was defective and/or unsafe for its intended use at the time of its design, manufacture, development, production, formulation, processing, testing, inspection, endorsement, prescription, promotion, sale and/or distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities and risks, including but not limited to the risk that Digitek® tablets contained or may contain a dose of digoxin inconsistent with the dose on the label, and thus, ingestion could lead to serious injuries, side effects and/or death.

59. At all times herein mentioned, the aforementioned drug was defective, and/or unsafe, and Defendants knew that Digitek® was to be used by the consumer and patients without inspection and/or knowledge of the increased risk of adverse health effects set forth herein. Moreover, Davis neither knew, nor had reason to know at the time of the use of Digitek®, of the existence of the aforementioned side effects, deleterious health risks and/or increased risk of health hazards or death.

60. Davis used Digitek® in a manner for which it was prescribed and/or reasonably and/or foreseeably intended.

61. Defendants failed to provide proper warning to users, healthcare professionals, and the public that Digitek® may contain amounts of digoxin exceeding or that was inconsistent with the amount on the label, and thus, ingestion could lead to serious injuries, side effects and/or death;

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and that any warnings given did not adequately reflect the potential symptoms, the scope of severity of side effects or the increased risk of health hazards posed.

62. Said Defendants intentionally proceeded with the manufacture, sale, promotion, and/or distribution and marketing of Digitek® with actual or constructive knowledge that persons would be exposed to serious risks of potential harm, injury and even death in order to advance its own pecuniary interests.

63. Prior to the manufacture, promotion, sale and/or distribution of Digitek®, Defendants knew that the product was defective and/or unsafe as previously described, and knew that those who used Digitek® in connection with medical care and treatment would experience, and/or would be exposed to an increased risk of severe physical injuries. Further, Defendants, through its officers, directors and managing agents, had prior notice and knowledge from several sources, prior to the date of the promotion, sale or distribution of said products to Davis, that the drug presented a risk of increased harm to the public, including Davis, and as such, persons exposed to Digitek® were unreasonably subjected to risk of injury, harm, or death.

64. As a legal cause of the defective condition of the aforementioned product, Davis died, and Plaintiffs suffered injuries and damages as alleged herein.

65. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

66. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

67. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

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FOURTH CAUSE OF ACTION

(Strict Product Liability – Manufacturing Defect)

As for a Fourth Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

68. Plaintiffs hereby incorporate by reference all paragraphs hereinabove as if fully set forth in detail below.

69. At all times mentioned, Defendants were engaged in the business of researching, licensing, designing, testing, manufacturing, producing, processing, assembling, formulating, inspecting, distributing, marketing, labeling, promoting, packaging, warning, advertising, and/or distributing Digitek® in the State of California.

70. At all times mentioned, Digitek® was expected to reach, and did reach, consumers throughout the United States and California, including Davis, without substantial change in the condition in which it was sold.

71. At all times mentioned, Digitek® contained a manufacturing defect and was not suitable for its intended purpose because it deviated from the formulas approved by the FDA and/or deviated from the formulas approved or allowed by the FDA and/or deviated from the design specifications, formulas, or standards of other Digitek® manufactured by Defendants for sale in the United States.

72. At all times mentioned, Digitek® herein above described was defective, and Defendants, and each of them, knew that the said drug would be used without inspection for defects therein. Moreover, Davis, neither knew, nor had reason to know at the time of the use of said drug, of the existence of the aforementioned defect or increased risk of harm.

73. As a legal cause of the defective condition of the aforementioned product, Davis died, and Plaintiffs suffered injuries and damages as alleged herein.

74. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

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75. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

76. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

FIFTH CAUSE OF ACTION

(Fraud and Deceit)

As for a Fifth Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

77. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

78. At all times during which Defendants tested, inspected, produced, manufactured, sold, distributed, marketed, processed, promoted or supplied Digitek® and up to the present, Defendants knowingly, intentionally, willfully and purposefully deceived Davis by: (1) making false and fraudulent misrepresentations to Davis, healthcare professionals and the general public including, but not limited to that said product was safe, fit and/or effective for the treatment of congestive heart failure, irregular heartbeat such as atrial fibrillation and atrial flutter, and/or other heart ailments; and (2) concealing from Davis, healthcare professionals and the general public the true facts concerning said drug.

79. At all times relevant to this action, Defendants knew that their representations were in fact false and inaccurate. The true and accurate facts, knowingly and intentionally concealed by Defendants were that the drug may contain amounts of digoxin exceeding or inconsistent with the amount on the label, and that over-dosage use of Digitek® is associated with life threatening hearth rhythm disturbances, cardiac instability, irregular pulse, heart palpitations, bradycardia, nausea, vomiting, diarrhea, dizziness, confusion, loss of appetite, visual disturbances, low blood pressure and even death. This information was known to the Defendants, who intentionally withheld this information from Plaintiff and other customers who purchased and ingested Digitek®.

80. At all times during which Defendants made the above-mentioned misrepresentations to Davis and other consumers of Digitek®, Defendants knew that the misrepresentations were false and inaccurate. Defendants made the misrepresentations with intent to deceive Davis, healthcare professionals and the public, and with the intent to induce Davis, healthcare professionals and the public and to choose Digitek® as their drug of choice.

81. Davis had no knowledge of the falsity of Defendants' misrepresentations, and in reliance upon Defendants' misrepresentations, believed Digitek® to be safe for consumption.

82. Davis and/or his healthcare professionals reasonably relied upon Defendants' misrepresentations, and was induced to and did, in fact, consume and ingest Digitek®, in combination to control his arrhythmia. Davis would not have consumed and ingested Digitek®, or a combination thereof, had he known and had he been informed of the true facts concerning the significantly increased risk associated with the use of the drug, and the aforementioned severe and life-threatening medical injuries attendant to these risks.

83. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale, distribution and consumption of Digitek® and willfully deceived Davis, healthcare professionals, and the general public as to the health risks and consequences of Digitek® when consumed. These representations were made directly by said Defendants to Davis and/or his healthcare professionals, by sales representatives and other authorized agents of said Defendants and in publications and other written materials directed to Davis, healthcare professionals, medical patients and the public, which were designed and/or intended to influence Davis' use of Digitek® to manage and/or control his symptoms of arrhythmia.

84. The foregoing representations and concealment by Defendants were made and conducted with the intent to willfully induce Davis to use, consume and ingest Digitek® for treatment of the decedent's arrhythmia.

85. As a legal result of the foregoing fraudulent and deceitful conduct by the Defendants, Davis purchased, consumed and ingested the Digitek® manufactured, distributed, marketed and sold by Defendants.

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86. As a legal cause of Defendants' fraudulent conduct, Davis ingested Digitek® and died, and Plaintiffs suffered injuries and damages as alleged herein.

87. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

88. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

89. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for the relief hereinafter set forth.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation)

As for a Sixth Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

90. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

91. At all times during which Defendants tested, inspected, produced, manufactured, sold, distributed, marketed or promoted Digitek®, Defendants falsely and negligently represented to Davis, the public and healthcare professionals that Digitek® was safe, fit and/or effective for the treatment of congestive heart failure, irregular heartbeat such as atrial fibrillation and atrial flutter, and/or other heart ailments.

92. At all times relevant to this action, Defendants knew, or should have known, that their representations were, in fact, false and inaccurate. The true and accurate facts knowingly and intentionally concealed by Defendants were that the drug may contain amounts of digoxin exceeding or inconsistent with the amount on the label, and that over-dosage use of Digitek® is associated with life threatening hearth rhythm disturbances, cardiac instability, irregular pulse, heart palpitations,

bradycardia, nausea, vomiting, diarrhea, dizziness, confusion, loss of appetite, visual disturbances, low blood pressure and even death.

93. At all times during which Defendants made the above-mentioned misrepresentations, they knew, or should have known, and had the ability and means to ascertain, that the representations concerning the safety of the drug were false, inaccurate and/or misleading.

94. Davis had no knowledge of the falsity of Defendants' representations and believed Digitek® to be safe for consumption.

95. Davis and/or his healthcare professionals reasonably relied upon Defendants' misrepresentations and was induced to and did purchase, consume and ingest Digitek®, or some combination thereof, as manufactured, distributed and sold by Defendants to treat his arrhythmia. Davis would not have purchased, ingested and consumed Digitek® if he had known the true facts concerning the significantly increased risk of adverse health effects associated with use of the drug and the attendant consequences of these risks upon his physical well-being.

96. As a legal cause of Defendants' negligent misrepresentations Davis ingested Digitek® and died, and Plaintiffs suffered injuries and damages as alleged herein.

97. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

98. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

99. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

SEVENTH CAUSE OF ACTION

(Negligence and Negligence Per Se)

As for a Seventh Cause of Action against Defendants, Plaintiffs are informed and believe, and thereon allege:

100. Plaintiffs hereby incorporate by reference all paragraphs above as if fully set forth in detail herein.

101. At all times herein mentioned, Defendants had a duty to exercise reasonable care in the manufacture, design, testing, producing, processing, assembling, formulation, inspecting, researching, quality assurance, quality control, distributing, marketing, advertising, promoting, labeling, packaging, preparing for use, sales, recalling and/or adequate warning of the risks and dangers of the over-dosage of Digitek®, including the duty to ensure that the drug did not cause users to be exposed to unreasonable harm or injury, and/or the increased risk of adverse, harmful and/or potentially fatal side effects.

102. At all times herein mentioned, Defendants failed to exercise ordinary care and were negligent, careless, and/or reckless in the manufacture, design, production, formulation, processing, assembling, inspecting, distributing, marketing, advertising, promoting, labeling, packaging and/or introduction into commerce of Digitek®, and failed to exercise ordinary care and were negligent, careless and reckless by failing to adequately test and warn of the risks and dangers of Digitek®; and further, failed to exercise ordinary care in promptly conducting a recall of Digitek® or to warn exposed patients of the increased risk of harm or injury in that Defendants knew, or should have known, of the increased risk of harm or injury to an individual's physical health, which alone and/or in combination could produce serious illness or even death.

103. Defendants were negligent in the design, manufacture, testing, advertising, marketing, promoting, warning, recommending and sales of Digitek® in that they:

- Failed to use due care in designing, formulating, manufacturing, testing, inspecting and/or quality control of the drug Digitek®, so as to avoid the aforementioned adverse health risks to individuals using Digitek® to treat congestive heart failure, irregular heartbeat such as atrial fibrillation and atrial flutter, and other heart ailments;
- Failed to use due care and adequately label, test, inspect and/or provide proper warnings regarding all possible adverse side effects associated with the use of Digitek®, including that the drug may contain amounts of digoxin exceeding or that

were inconsistent with the amount on the label, and thus, ingestion could lead to serious injuries, side effects and/or death; and that any warnings given did not adequately reflect the potential symptoms, scope of severity of the side effects or the increased risk of health hazards posed;

- Failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety or health risks associated with the use of Digitek®;
- Failed to comply with and/or use reasonable care to comply with standards of Good Manufacturing Practices with respect to the manufacture, testing and/or inspection of Digitek®;
- Failed to recall Digitek® in a timely manner at a time when Defendants knew or should have known that Digitek® was a cause of injuries and deaths;
- Manufactured, designed, tested, distributed, inspected and/or sold Digitek® defectively, which constituted a hazard to health;
- Manufactured, designed, tested, distributed, inspected and/or sold Digitek® defectively, which caused adverse health effects and increased the risk of death in patients;

104. Despite the fact that Defendants knew, or should have known, that Digitek® caused unreasonable, dangerous side effects, which could result in serious injury or death, Defendants continued to market, advertise, distribute and sell Digitek® to users and patients such as Davis, when there were safer alternative drugs and methods to treat congestive heart failure, irregular heartbeat such as atrial fibrillation and atrial flutter, and other heart ailments.

105. Defendants knew or should have known that consumers, users and patients, such as Davis, would foreseeably suffer injury and/or death as a result of Defendants' failure to exercise ordinary care as described above.

106. At all times herein mentioned, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, *et seq.*, related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, California Health and Safety Code Sections 110290, 110390, 110395, 110398, 110400 and 111330, California Civil Code Sections

1750, 1790, *et seq.*, and regulations promulgated thereunder, and other applicable laws, statutes and regulations.

107. Davis, as a purchaser and consumer of Digitek®, is within the class of persons that the statutes and regulations described above are designed to protect, and Davis' injuries are the type of harm these statutes are designed to prevent.

108. As a legal cause of the defective condition of the aforementioned product, Davis died, and Plaintiffs suffered injuries and damages as alleged herein.

109. By reason of the premises and the wrongful death of Davis, Plaintiffs suffered and continue to suffer loss of love, companionship, comfort, affection, solace and moral support of their husband/father.

110. By reason of the premises of the wrongful death of Davis, Plaintiffs have incurred and/or will incur funeral and burial expenses in an amount to be determined at trial.

111. By reason of the wrongful death of Davis, resulting from the wrongful acts and/or omissions of Defendants, and each of them, Plaintiffs hereby seek recovery of other such relief as may be just and provided under Code of Civ. Proc. § 377.61.

WHEREFORE, Plaintiffs pray for relief as set forth below.

EIGHTH CAUSE OF ACTION

(Negligent Infliction of Emotional Distress On Behalf of Dephlia Davis Only)

As for a Eighth Cause of Action against Defendants, Plaintiff Dephlia Davis is informed and believes, and thereon alleges:

112. Plaintiff hereby incorporates by reference all paragraphs above as if fully set forth in detail herein.

113. At the time of Davis' tragic death, his wife Plaintiff Dephlia Davis, was in close proximity to him and personally witnessed his death.

114. Because of the negligent conduct of Defendants, and as a result thereof, Plaintiff Dephlia Davis sustained severe emotional distress and mental suffering, all of which has caused, continues to cause, and will cause her great physical and mental pain and suffering, all to her damage.

115. As a further legal result of said wrongful acts of Defendants, Plaintiff was required to and did employ physicians and/or physical therapists and other health care providers to examine, treat and care for her injuries, and has incurred, and will continue to incur, medical and incidental expenses for such examination, treatment and care in an amount according to proof.

116. At the time Plaintiff sustained said injuries, she was gainfully employed and/or capable of gainful employment. As a further legal result of the aforesaid conduct of the Defendants, and of the said injuries sustained thereby, Plaintiff has suffered a loss of income, and/or a loss of earning capacity, resulting in an economic loss in an amount according to proof.

PRAYER FOR RELIEF

1. For compensatory and general damages in a sum in excess of the jurisdictional minimum of this Court and according to proof;
2. For past and future medical, incidental, hospital services and expenses according to proof;
3. For past and future loss of earnings and earning capacity;
4. For prejudgment interest on all damages as is allowed by the law;
5. For attorneys' fees, expenses, and costs of the suit as allowed by law; and
6. Such other, further and different relief which the Court deems necessary, just and proper.

DATED: July 1, 2008

COTCHETT, PITRE & McCARTHY

By: Niki B. Okcu
FRANK M. PITRE
NIKI B. OKCU
Attorneys for Plaintiffs Dephlia Davis, Rhea Davis and Jesse Gaynor

JURY DEMAND

Plaintiffs demand trial by jury on all issues so triable.

DATED: July 1, 2008

COTCHETT, PITRE & McCARTHY

By: Niki B. Okcu
FRANK M. PITRE
NIKI B. OKCU
Attorneys for Plaintiffs Dephlia Davis, Rhea Davis and Jesse Gaynor